

CLAIMS

1. A pharmaceutical composition comprising:
  - a. an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof;
  - b. an amount of atorvastatin or a pharmaceutically acceptable salt thereof; and
  - c. a pharmaceutically acceptable carrier or diluent.
2. A pharmaceutical composition of claim 1 comprising amlodipine besylate.
3. A pharmaceutical composition of claim 2 comprising the hemicalcium salt of atorvastatin.
4. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antihypertensive effect and a hypolipidemic effect in a mammal suffering from hypertension and hyperlipidemia, which effects are greater than the sum of the antihypertensive and hypolipidemic effects achieved by administering said first and second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent.
5. A first pharmaceutical composition of claim 4 wherein said second pharmaceutical composition comprises amlodipine besylate.
6. A first pharmaceutical composition of claim 5 comprising the hemicalcium salt of atorvastatin.
7. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antihypertensive effect and a hypolipidemic effect in a mammal suffering from hypertension and hyperlipidemia, which effects are greater than the sum of the antihypertensive and hypolipidemic effects achieved by administering said first and second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically

acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

8. A first pharmaceutical composition of claim 7 comprising amlodipine besylate.

9. A first pharmaceutical composition of claim 8 wherein said second pharmaceutical composition comprises the hemicalcium salt of atorvastatin.

10. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antihypertensive effect and a hypolipidemic effect in a mammal suffering from hypertension and hyperlipidemia, which effects are greater than the antihypertensive and hypolipidemic effects achieved by administering said first or second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

11. A first pharmaceutical composition of claim 10 comprising amlodipine besylate.

12. A first pharmaceutical composition of claim 11 wherein said second pharmaceutical composition comprises the hemicalcium salt of atorvastatin.

13. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antihypertensive effect and a hypolipidemic effect in a mammal suffering from hypertension and hyperlipidemia, which effects are greater than the antihypertensive and hypolipidemic effects achieved by administering said first or second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent.

14. A first pharmaceutical composition of claim 13 wherein said second pharmaceutical composition comprises amlodipine besylate.

15. A first pharmaceutical composition of claim 14 comprising the hemicalcium salt of atorvastatin.

16. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antiangina effect in a mammal suffering from angina pectoris, which effect is greater than the sum of the antiangina effects achieved by administering said first and second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

17. A first pharmaceutical composition of claim 16 comprising amlodipine besylate.

18. A first pharmaceutical composition of claim 17 wherein said second pharmaceutical composition comprises the hemicalcium salt of atorvastatin.

19. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antianginal effect in a mammal suffering from angina pectoris, which effect is greater than the sum of the antiangina effects achieved by administering said first and second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent.

20. A first pharmaceutical composition of claim 19 wherein said second pharmaceutical composition comprises amlodipine besylate.

21. A first pharmaceutical composition of claim 20 comprising the hemicalcium salt of atorvastatin.

22. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antianginal effect in a mammal suffering from angina pectoris, which effect is greater than the antianginal effects achieved by administering said first or second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically

acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

acceptable carrier or diluent.

23. A first pharmaceutical composition of claim 22 comprising amlodipine besylate.

24. A first pharmaceutical composition of claim 23 wherein said second pharmaceutical composition comprises the hemicalcium salt of atorvastatin.

25. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antianginal effect in a mammal suffering from angina pectoris, which effect is greater than the antianginal effects achieved by administering said first or second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent.

26. A first pharmaceutical composition of claim 25 wherein said second pharmaceutical composition comprises amlodipine besylate.

27. A first pharmaceutical composition of claim 26 comprising the hemicalcium salt of atorvastatin.

28. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antiatherosclerotic effect in a mammal, which effect is greater than the sum of the antiatherosclerotic effects achieved by administering said first and second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent.

29. A first pharmaceutical composition of claim 28 wherein said second pharmaceutical composition comprises amlodipine besylate.

30. A first pharmaceutical composition of claim 29 comprising the hemicalcium salt of atorvastatin.

31. A composition of claim 30 wherein said antiatherosclerotic effect is manifested by a slowing of the progression of atherosclerotic plaques.

32. A composition of claim 31 wherein said progression of atherosclerotic plaques is slowed in coronary arteries.

33. A composition of claim 31 wherein said progression of atherosclerotic plaques is slowed in carotid arteries.

34. A composition of claim 31 wherein said progression of atherosclerotic plaques is slowed in the peripheral arterial system.

35. A composition of claim 30 wherein said antiatherosclerotic effect is manifested by a regression of atherosclerotic plaques.

36. A composition of claim 35 wherein said regression of atherosclerotic plaques occurs in coronary arteries.

37. A composition of claim 35 wherein said regression of atherosclerotic plaques occurs in carotid arteries.

38. A composition of claim 35 wherein said regression of atherosclerotic plaques occurs in the peripheral arterial system.

39. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antiatherosclerotic effect in a mammal, which effect is greater than the sum of the antiatherosclerotic effects achieved by administering said first and second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

40. A first pharmaceutical composition of claim 39 comprising amlodipine besylate.

41. A first pharmaceutical composition of claim 40 wherein said second pharmaceutical composition comprises the hemicalcium salt of atorvastatin.

42. A composition of claim 41 wherein said antiatherosclerotic effect is manifested by a slowing of the progression of atherosclerotic plaques.

43. A composition of claim 42 wherein said progression of atherosclerotic plaques is slowed in coronary arteries.

44. A composition of claim 42 wherein said progression of atherosclerotic plaques is slowed in carotid arteries.

45. A composition of claim 42 wherein said progression of atherosclerotic plaques is slowed in the peripheral arterial system.

46. A composition of claim 41 wherein said antiatherosclerotic effect is manifested by a regression of atherosclerotic plaques.

47. A composition of claim 46 wherein said regression of atherosclerotic plaques occurs in coronary arteries.

48. A composition of claim 46 wherein said regression of atherosclerotic plaques occurs in carotid arteries.

49. A composition of claim 46 wherein said regression of atherosclerotic plaques occurs in the peripheral arterial system.

50. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antiatherosclerotic effect in a mammal, which effect is greater than the antiatherosclerotic effects achieved by administering said first or second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

51. A first pharmaceutical composition of claim 50 comprising amlodipine besylate.

52. A first pharmaceutical composition of claim 51 wherein said second pharmaceutical composition comprises the hemicalcium salt of atorvastatin.

53. A composition of claim 52 wherein said antiatherosclerotic effect is manifested by a slowing of the progression of atherosclerotic plaques.

54. A composition of claim 53 wherein said progression of atherosclerotic plaques is slowed in coronary arteries.

55. A composition of claim 53 wherein said progression of atherosclerotic plaques is slowed in carotid arteries.

56. A composition of claim 53 wherein said progression of atherosclerotic plaques is slowed in the peripheral arterial system.

57. A composition of claim 52 wherein said antiatherosclerotic effect is manifested by a regression of atherosclerotic plaques.

58. A composition of claim 57 wherein said regression of atherosclerotic plaques occurs in coronary arteries.

59. A composition of claim 57 wherein said regression of atherosclerotic plaques occurs in carotid arteries.

60. A composition of claim 57 wherein said regression of atherosclerotic plaques occurs in the peripheral arterial system.

61. A first pharmaceutical composition for use with a second pharmaceutical composition for achieving an antiatherosclerotic effect in a mammal, which effect is greater than the antiatherosclerotic effects achieved by administering said first or second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent.

62. A first pharmaceutical composition of claim 61 wherein said second pharmaceutical composition comprises amlodipine besylate.

63. A first pharmaceutical composition of claim 62 comprising the hemicalcium salt of atorvastatin.

64. A composition of claim 63 wherein said antiatherosclerotic effect is manifested by a slowing of the progression of atherosclerotic plaques.

65. A composition of claim 64 wherein said progression of atherosclerotic plaques is slowed in coronary arteries.

66. A composition of claim 64 wherein said progression of atherosclerotic plaques is slowed in carotid arteries.

67. A composition of claim 64 wherein said progression of atherosclerotic plaques is slowed in the peripheral arterial system.

68. A composition of claim 63 wherein said antiatherosclerotic effect is manifested by a regression of atherosclerotic plaques.

69. A composition of claim 68 wherein said regression of atherosclerotic plaques occurs in coronary arteries.

70. A composition of claim 68 wherein said regression of atherosclerotic plaques occurs in carotid arteries.

71. A composition of claim 68 wherein said regression of atherosclerotic plaques occurs in the peripheral arterial system.

72. A first pharmaceutical composition for use with a second pharmaceutical composition for managing cardiac risk in a mammal at risk of suffering an adverse cardiac event, which effect is greater than the sum of the cardiac risk management effects achieved by administering said first and second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

73. A first pharmaceutical composition of claim 72 comprising amlodipine besylate.

74. A first pharmaceutical composition of claim 73 wherein said second pharmaceutical composition comprises the hemicalcium salt of atorvastatin.

75. A first pharmaceutical composition for use with a second pharmaceutical composition for managing cardiac risk in a mammal at risk of suffering an adverse cardiac event, which effect is greater than the sum of the cardiac risk management effects achieved by administering said first and second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

76. A first pharmaceutical composition of claim 75 wherein said second pharmaceutical composition comprises amlodipine besylate.

77. A first pharmaceutical composition of claim 76 comprising the hemicalcium salt of atorvastatin.

78. A first pharmaceutical composition for use with a second pharmaceutical composition for managing cardiac risk in a mammal at risk of suffering an adverse cardiac event, which effect is greater than the cardiac risk management effects



achieved by administering said first or second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent.

79. A first pharmaceutical composition of claim 78 comprising amlodipine besylate.

80. A first pharmaceutical composition of claim 79 wherein said second pharmaceutical composition comprises the hemicalcium salt of atorvastatin.

81. A first pharmaceutical composition for use with a second pharmaceutical composition for managing cardiac risk in a mammal at risk of suffering an adverse cardiac event, which effect is greater than the cardiac risk management effects achieved by administering said first or second pharmaceutical compositions separately and which second pharmaceutical composition comprises an amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent, said first pharmaceutical composition comprising an amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent.

82. A first pharmaceutical composition of claim 81 wherein said second pharmaceutical composition comprises amlodipine besylate.

83. A first pharmaceutical composition of claim 82 comprising the hemicalcium salt of atorvastatin.

84. A kit for achieving a therapeutic effect in a mammal comprising:

a. a therapeutically effective amount of amlodipine or a pharmaceutically acceptable acid addition salt thereof and a pharmaceutically acceptable carrier or diluent in a first unit dosage form;

b. a therapeutically effective amount of atorvastatin or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier or diluent in a second unit dosage form; and

c. container means for containing said first and second dosage forms.

85. A kit of claim 84 comprising amlodipine besylate.

86. A kit of claim 85 comprising the hemicalcium salt of atorvastatin.
87. A kit of claim 86 wherein said therapeutic effect is treatment of hypertension and hyperlipidemia.
88. A kit of claim 86 wherein said therapeutic effect is treatment of angina pectoris.
89. A kit of claim 86 wherein said therapeutic effect is management of cardiac risk.
90. A kit of claim 86 wherein said therapeutic effect is treatment of atherosclerosis.
91. A kit of claim 90 wherein said treatment of atherosclerosis slows the progression of atherosclerotic plaques.
92. A kit of claim 91 wherein said progression of atherosclerotic plaques is slowed in coronary arteries.
93. A kit of claim 91 wherein said progression of atherosclerotic plaques is slowed in carotid arteries.
94. A kit of claim 91 wherein said progression of atherosclerotic plaques is slowed in the peripheral arterial system.
95. A kit of claim 90 wherein said treatment of atherosclerosis causes the regression of atherosclerotic plaques.
96. A kit of claim 95 wherein said regression of atherosclerotic plaques occurs in coronary arteries.
97. A kit of claim 95 wherein said regression of atherosclerotic plaques occurs in carotid arteries.
98. A kit of claim 95 wherein said regression of atherosclerotic plaques occurs in the peripheral arterial system.
99. A method for treating a mammal in need of therapeutic treatment comprising administering to said mammal
- (a) an amount of a first compound, said first compound being amlodipine or a pharmaceutically acceptable acid addition salt thereof; and
  - (b) an amount of a second compound, said second compound being atorvastatin or a pharmaceutically acceptable salt thereof;

wherein said first compound and said second compound are each optionally and independently administered together with a pharmaceutically acceptable carrier or diluent.

100. A method of claim 99 comprising amlodipine besylate.
101. A method of claim 100 comprising the hemicalcium salt of atorvastatin.
102. A method of claim 99 wherein said first compound and said second compound are administered simultaneously.
103. A method of claim 99 wherein said first compound and said second compound are administered sequentially in either order.
104. A method of claim 101 wherein said first compound and said second compound are administered simultaneously.
105. A method of claim 101 wherein said first compound and said second compound are administered sequentially in either order.
106. A method of claim 99 wherein said therapeutic treatment comprises antihypertensive treatment and antihyperlipidemic treatment.
107. A method of claim 104 wherein said therapeutic treatment comprises antihypertensive treatment and antihyperlipidemic treatment.
108. A method of claim 105 wherein said therapeutic treatment comprises antihypertensive treatment and antihyperlipidemic treatment.
109. A method of claim 99 wherein said therapeutic treatment comprises antianginal treatment.
110. A method of claim 104 wherein said therapeutic treatment comprises antianginal treatment.
111. A method of claim 105 wherein said therapeutic treatment comprises antianginal treatment.
112. A method of claim 99 wherein said therapeutic treatment comprises cardiac risk management.
113. A method of claim 104 wherein said therapeutic treatment comprises cardiac risk management.
114. A method of claim 105 wherein said therapeutic treatment comprises cardiac risk management.
115. A method of claim 99 wherein said therapeutic treatment comprises antiatherosclerotic treatment.

117. A method of claim 105 wherein said therapeutic treatment comprises antiatherosclerotic treatment.

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